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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.        | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------------|------------------|
| 09/800,198   | 03/05/2001  | Corine Vermet        | 15966-697 CURA-197)        | 5015             |
| 30623  | 7590        | 03/16/2004           |                            |                  |
| MINTZ, LEVIN, COHN, FERRIS, GLOVSKY<br>AND POPEO, P.C.<br>ONE FINANCIAL CENTER<br>BOSTON, MA 02111 |             |                      | EXAMINER<br>HAMUD, FOZIA M |                  |
|  |             |                      | ART UNIT                   | PAPER NUMBER     |
|  |             |                      | 1647                       |                  |

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/800,198

Applicant(s)

VERMET ET AL.

Examiner

Fozia M Hamud

Art Unit

1647

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 12 November 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☒ affidavit, b) ☒ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1, 3, 4, AND 5

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_.

### **ADVISORY ACTION**

1a. Receipt of Applicant's amendment and arguments, filed on 12 November 2003, is acknowledged. Claims 38 and 41 have been amended, and new claim 56 has been added. Claims 1, 38, 41 and 56 are pending.

1b. Receipt of Applicants' declarations under 37 C.F.R §1.132, filed by Seth Ettnerberg and Xiaojia Guo on 12 November 2003 is also acknowledged.

### ***Claim Rejections - 35 U.S.C. § 101/112***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2a. Claims 1, 38, 41 and 56 stand rejected under 35 U.S.C. § 101, for reasons of record, set forth in the office actions mailed on 09/27/03 and 06/16/03, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Most of the arguments presented by the Applicants have been previously addressed, only new arguments will be addressed below.

Applicants argue that the present application describes differential expression of NOV3b in human glioma, astrocytoma, renal, breast and ovarian carcinomas and melanoma, and cites page 94, lines 15-18, of the instant specification as providing support for said differential expression.

Firstly, the data in Exhibit A has been addressed in the final office action mailed on 16 June 2003, pages 2-4. Secondly, page 94, of the substitute specification, discloses that predicted disease indications for FCTR3 include gliomas, astrocytomas, mixed glioma/astrocytomas, renal cells carcinoma, breast adenocarcinoma. However,

Art Unit: 1647

the instant specification discloses numerous nucleic acids and encoded polypeptides termed as FCTR3a-I, (see tabled 8a, on pages 122), of which FCTR3b is the claimed polypeptide of SEQ ID NO:8, which comprises 2733 amino acid residues. Therefore, the generic statement that FCTR3 polypeptides might be involved in the mentioned diseases does not support the data on Exhibit A, because the specification does not disclose whether the polypeptide of SEQ ID NO:8 is overly expressed in any of these cancers. (Applicants' arguments address NOV3b, which is not found anywhere in the specification, it is understood that NOVb3 is the same as the polypeptide of SEQ ID NO:8, which is designated as FCT3b on page 36, lines 41-44 of the specification).

Applicants argue that the Pennica reference does not disclose protein expression at all, and that it was a surprise to Pennica that there was a lack of correlation between gene number and RNA expression. Thus, Applicants contend that one skilled in the art more likely than not would expect there is a direct correlation between transcript level and corresponding expression.

Applicants are correct that the Pennica et al reference does not demonstrate a relationship between protein expression and corresponding mRNA expression. However, Pennica et al demonstrated that there was a lack of correlation between gene number and RNA expression, and although this might have been surprising to the authors, nevertheless, this demonstrates that protein levels cannot be accurately predicted from the level of the corresponding gene.

2b. The claimed invention also stands rejected under 35 U.S.C. 112, first paragraph, since the claimed invention is not supported by either a specific and substantial

asserted utility or a well established utility for the reasons set forth above, because one skilled in the art clearly would not know how to use it.

3. ***Declaration under 37 C.F.R §1.132:***

3a. Applicants' declaration under 37 C.F.R §1.132, filed by Xiaojia Guo on 12 November 2003 has been considered, but is insufficient to overcome the rejection of claims 1, 38, 41 and 56, made under 35 U.S.C. § 101-112.

The declaration submitted by Xiaojia Guo, pertains to the fact that the nucleic acid encoding the claimed polypeptide is expressed in certain tumors, compared to normal controls. As was stated in the final office action mailed on 16 June 2003, this data establishes an asserted utility that is specific, substantial and credible for the DNA. However, the increased copy number of DNA does not provide a readily apparent use for the polypeptide, because there is no information regarding the level of expression, an activity, or a role in cancer for the polypeptide.

3a. Applicants' declaration under 37 C.F.R §1.132, filed by Seth Ettenberg on 12 November 2003 has been considered, but is insufficient to overcome the rejection of claims 1, 38, 41 and 56, made under 35 U.S.C. § 101-112.

Dr. Ettenberg demonstrates that the polypeptide of SEQ ID NO:8 is detected in various cancer cell lines. However, established cell lines (which are kept alive in cell culture for a significant length of time), have undergone numerous phenotypic changes and may differ dramatically from the tumor which they were isolated. Therefore, polypeptides that are expressed in these established cell lines may have no relevance on the original tumors. Cells from freshly isolated tumors that are kept alive on a short-

Art Unit: 1647

term basis in cell culture, are more appropriate model systems, because these cells are phenotypically the same as the tumor from which they were isolated.

Therefore, the fact that the claimed polypeptide of SEQ ID NO:8 is expressed in various cancer cell lines does not establish an asserted utility that is specific, substantial and credible for the polypeptide, because Applicants have not shown that the claimed polypeptide is expressed in the original tumors.

**Conclusion:**

4. No claim is allowed.

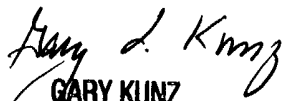
**Advisory Information:**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
12 March 2004

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600